

B589



**Bentley Pharmaceuticals**  
**Project Status Report – January 11, 2002**

PROJECT AND STATUS	ACTION
e) 5 <sup>th</sup> Patent – New procedure for tablets – direct compression. Plan to submit in December 2001. f) PCT for Paracetamol filed (Spanish Patent: P200002653)  ▪ <u>Patents – Bentley</u> a) Intranasal Insulin Patent – Bob G. filed the provisional in U.S. in June '01. b) Lacquer PCT published 23 Aug (PCT/US01/05302)	
31. BOD Meeting Schedule ▪ Jan meeting postponed to 21-22 Feb (tentative) in North Hampton.  <u>Other meetings:</u> The spring shareholder meeting is tentatively scheduled for May 22 <sup>nd</sup> , don't want AMEX Board Rm, possibly the Penn Club. Jordan check with Miguel.	Plan for Feb BOD meeting   Jordan follow up with Miguel on availability of Penn Club for Shareholder mtg
<b>END LIST- OTHER POTENTIALS</b>  McNeil – Lacquer Schering AG (Berlex in U.S.) – Derm. products, HRT PLR – Potential switch to other firm Helm – paracetamol Lavipharma – SkyePharma – Spain, JV Angelini  <u>Acquisition Potentials</u> (Bayvit, Dermtech, BioConcepts, Labs Argenol)	

**CONFIDENTIAL**

5

**BENTL022502**  
**HIGHLY CONFIDENTIAL**

B590

**From:** Paul Fitzgibbons

**Sent:** Tue, 22 Jan 2002 15:46:55 GMT

**To:** 'Bolling Charles (Chick) (E-mail)'; 'Packer William (E-mail)'; 'McGovern Mike (E-mail)'; 'Fernandez Miguel (E-mail)'; Jim Murphy; Mike Price; 'Stote Bob (E-mail)'; Bob Gyurik

**CC:** Jordan Horvath

**BCC:**

**Subject:** Bentley Operations Update

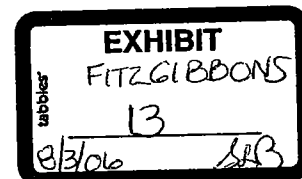
Attached is the Bentley Operations Update that I periodically distribute to the Board of Directors. I have also faxed a copy to outside Directors just in case email receipt is difficult or fails. Please call me if you have any questions.

Paul Fitzgibbons

Bentley Pharmaceuticals, Inc.

603-964-8006 (office) 603-964-6889 (fax)

pfitzgibbons@bentleypharm.com



BENTL003104  
HIGHLY CONFIDENTIAL

B591

To: Bentley Pharmaceuticals Board of Directors  
From: Paul Fitzgibbons

Subject: Operations Update 22 January 2002

Below is the Operations Update that is periodically distributed to the Board of Directors. The update highlights many of the key activities that are discussed at our company management meetings. It is organized into three areas: 1) Spain Activities; 2) Product Development; and 3) Licensing Activities. Suggestions are welcome. Please contact me or Jim if you have questions relating to any specific activity.

---

**Bentley Pharmaceuticals Operations Update – 22 January 2002**

**1. Spain Activities**

- a. Filed four new patents for Improved Orally Delivered Products, including omeprazole and lansoprazole. Press release issued November 14, 2001.
- b. Prepared for potential Phase III lacquer study in Spain. Currently awaiting direction from the Novartis collaboration, or Pharmacia, before proceeding with this new trial.
- c. New specialized manufacturing equipment installed and operating (vacuum desiccation).
- d. Additional 800 Kg & 300 Kg micro granulation equipment installed for expanded omeprazole manufacturing. Expect to increase contract manufacturing by 50% for Year 2002.
- e. Ethypharm customers for omeprazole in process of re-contracting with Lab. Belmac.
- f. Simvastatin approved earlier than expected – launched 17 Jan 2002, first to market! We will be manufacturing for approximately eight other companies also.
- g. Budget for 2002 in established products is for \$32 mil (approx 35% growth).
- h. Turned down opportunity to manufacture for Novartis – margins too low.
- i. Key personnel/staff changes:
  - Jose Maria (finance) retiring; Ester will replace
  - Fernando Bereunger retiring; new MD hired
  - Clemente Gonzales retiring; new MD hired
- j. Teva has committed to accelerate 15 new registrations through either Spain National Submission or the Mutual Recognition procedure. Teva is exploring acquisition of Bayvit

CONFIDENTIAL

1

**BENTL003105  
HIGHLY CONFIDENTIAL**

B592

(No. 2 Generic in Spain). If this occurs, then the products would be transferred to Lab. Belmac/Davur.

k. Generic Drug Submissions for Yr 2002

**Laboratorios Belmac - YR 2002 Planned Generic Drug Submissions**

- |                                  |                              |
|----------------------------------|------------------------------|
| (3) *Omeprazole (Prilosec®)      | (2) Carbidopa-Levodopa       |
| (2) Bisoprolol 5 & 10mg          | (3) Pergolide (Permax®)      |
| (2) Doxazosine                   | (5) Lisinopril (Prinivil®)   |
| (1) Zolpiden (Ambien®)           | (3) Pravastatin (Pravachol®) |
| (2) Amox/Clavulanic (Augmentin®) | (4) Mirtazapine (Remeron®)   |
| (3) Amox/Clavulanic suspension   | (5) Fluconazole (Diflucan®)  |
| (1) Ibuprofen 100mg suspension   | (1) Famotidine (Pepcid®)     |
| (3) *Paracetamol sachets         | (2) Amoxicillin sachets      |
| (3) *Paracetamol tablets         | (3) Acetylcysteine           |
| (1) Paroxetine (Paxil®)          | (1) Naltrexone (ReVia®)      |
| (1) Amoxicillin suspension       |                              |

(#) = dosage levels      \* = BNT Patents

**2. Product Development**

a. Onychomycosis (Nail Lacquer) – The fingernail/toenail lacquer trials at the University of Alabama-Birmingham have continued to show excellent results. Trials (fingernail) will complete in March. Toenail Studies are trending even better than the Fingernail Studies. The PCT (Patent Cooperation Treaty) patent was filed worldwide and published in August 2001. Subsequent individual country filings are pending.

b. Intranasal Insulin –

- 1) Have source of insulin supply from Diosynth (Akzo-Nobel, Netherlands); insulin supply agreement signed.
- 2) Insulin cGMP manufacturing has been accomplished by BioConcepts Labs in Derry, NH.
- 3) Initial Proof of Principal trial in normal volunteers to be conducted in January (initiated on 18 Jan) in collaboration with the University of New Hampshire and a contract clinic.
- 4) Follow-on Phase I/II trials at the Diabetes and Glandular Disease Clinic, San Antonio, TX (PI - Sherwyn Schwartz) anticipated along with collaboration with GSK or another large company.

c. Testosterone for men – Phase III testosterone in men completed by Auxilium A2. The NDA was submitted 31 December. Working closely with Auxilium A2 on terms of disclosure and timing of press release for results and filing of NDA.

CONFIDENTIAL

2

**BENTL003106  
HIGHLY CONFIDENTIAL**

B593

d. Androstanolone (DHT) and Oxycodone – Signed letter of intent with Auxilium A2. Funding provided from Auxilium for formulation development. Currently, Auxilium A2 is evaluating DHT formulations that we delivered to them. Oxycodone is on hold for the time being and may be substituted with another pain management agent.

e. Dartmouth – Testosterone gel trial in women with Fibromyalgia / Chronic Fatigue Syndrome commenced in December at the Dartmouth-Hitchcock Medical Center in Hanover, NH. Initial results with the first group of patients are promising. The trial will be continuing January - April with additional patients. An update on analysis of data for the first group is expected later this month from Dartmouth.

f. University of New Hampshire (UNH) Studies – Three studies/grants from the New Hampshire Industrial Research Committee in collaboration with UNH are in process. The third grant was approved this past summer. Studies include:

- 1) Formulation studies for nail lacquer, intranasal insulin spray
- 2) Hormone gels and intranasal spray testing in animals
- 3) Topical and intranasal study of the growth hormone (GnRH) for fertility applications

g. Paracetamol – Results of clinical study comparing paracetamol (1g sachet, two 500 mg tablets swallowed, and two 500 mg tablets dissolved) against reference drugs, Panadol® (GSK) and Tylenol® (McNeil), were completed in the third quarter last year. Results showed that Paracetamol outperformed both reference drugs by achieving maximum blood concentration in approximately one half the time of the reference drugs. Results announced in an October 2001 press release.

h. Simvastatin – Completed bioavailability studies of Simvastatin (Merck's Zocor®) – Bioequivalent and launched.

### 3. Licensing Activities

a. Pfizer – Following the successful Pfizer evaluation of our formulations (blind products) over the past 8 months, Pfizer signed a Research Collaboration Agreement with Bentley in December. The press release was issued on December 3rd. A joint working team has been formed, and Pfizer has agreed to fund \$310K for initial formulation development and in vitro testing (\$250K already received). Products include two veterinary products (Doramectin and Selamectin), and three unknown human products (one sexual health, and two anti-virals). Formulation development is in progress with in-vitro testing (human skin, Franz cell) planned for mid-February at DermTech.

#### b. Novartis –

- 1) Negotiations/agreements are in process for nail lacquer collaboration. Material Transfer Agreement and terms of agreement in process. Plan entails a multi-site Phase III trial for lacquers (with CPE-215) for potential actives: Terbinafine, Clotrimazole, Naftifine. Novartis wants to proceed with OTC as well as Rx. Visit to Basel, Switzerland to coordinate is scheduled for 5 February.

CONFIDENTIAL

3

BENTL003107  
HIGHLY CONFIDENTIAL

- 2) Novartis also has continuing interest in a potential collaboration for paracetamol; discussion here is open and continuing.
- 3) Novartis asked to expand collaboration to include broad application of antifungals and other Rx products.

c. GlaxoSmithKline (GSK) –

- 1) Continuing interest in our intranasal insulin. GSK completed due diligence on us in July. After internal review by various groups/committees, GSK holding further progress until completion of our proof of principal insulin trial, which commences 18 January in North Hampton, NH.
- 2) GSK also interested in collaboration for transdermal formulation development.

d. Pharmacia – They have strong interest in our nail lacquer. Pharmacia conducted due diligence at Bentley in October. Notified us of intent to negotiate OTC license Jan/Feb. Negotiations/discussion of collaboration continuing.

e. Cambrex – Desire percentage interest in Bentley and establishment of JV Company to explore various product development in U.S. as well as generic filings in U.S. Exploratory discussions are underway.

f. Bristol Myers Squibb (BMS) – Continuing interest in intranasal insulin and other proprietary peptides. Meeting held 17 January.

g. Current licensing activity for paracetamol:

- Herron
- Sanofi
- Reckitt-Benckiser
- Perrigo
- Banner
- Chattem
- Angelini
- Bristol Myers Squibb
- Pharmacia
- Helm

h. Other Potential Drug Delivery, or other Company Collaborations are underway with:

- |                 |                      |
|-----------------|----------------------|
| • SkyePharma    | • Angelini           |
| • Perrigo       | • Schering AG/Berlex |
| • DUSA          | • Ardent Pharma      |
| • Lavipharma    | • DermTech           |
| • Chattem       | • Bio-Concepts Labs  |
| • Banner Pharma | • Labs Argenol       |
| • Helm          | • Medipointe         |
| • Bayvit/TEVA   | • Cephalon           |
| • Bayer         |                      |

CONFIDENTIAL

B595

**From:** Paul Fitzgibbons

**Sent:** Tue, 22 Jan 2002 15:46:55 GMT

**To:** 'Bolling Charles (Chick) (E-mail)'; 'Packer William (E-mail)'; 'McGovern Mike (E-mail)'; 'Fernandez Miguel (E-mail)'; Jim Murphy; Mike Price; 'Stote Bob (E-mail)'; Bob Gyurik

**CC:** Jordan Horvath

**BCC:**

**Subject:** Bentley Operations Update

---

Attached is the Bentley Operations Update that I periodically distribute to the Board of Directors. I have also faxed a copy to outside Directors just in case email receipt is difficult or fails. Please call me if you have any questions.

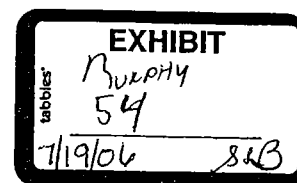
Paul Fitzgibbons

Bentley Pharmaceuticals, Inc.

603-964-8006 (office) 603-964-6889 (fax)

pfitzgibbons@bentleypharm.com

---



BENTL024412  
HIGHLY CONFIDENTIAL

B596

To: Bentley Pharmaceuticals Board of Directors  
From: Paul Fitzgibbons

Subject: Operations Update 22 January 2002

Below is the Operations Update that is periodically distributed to the Board of Directors. The update highlights many of the key activities that are discussed at our company management meetings. It is organized into three areas: 1) Spain Activities; 2) Product Development; and 3) Licensing Activities. Suggestions are welcome. Please contact me or Jim if you have questions relating to any specific activity.

---

### **Bentley Pharmaceuticals Operations Update – 22 January 2002**

#### **1. Spain Activities**

- a. Filed four new patents for Improved Orally Delivered Products, including omeprazole and lansoprazole. Press release issued November 14, 2001.
- b. Prepared for potential Phase III lacquer study in Spain. Currently awaiting direction from the Novartis collaboration, or Pharmacia, before proceeding with this new trial.
- c. New specialized manufacturing equipment installed and operating (vacuum desiccation).
- d. Additional 800 Kg & 300 Kg micro granulation equipment installed for expanded omeprazole manufacturing. Expect to increase contract manufacturing by 50% for Year 2002.
- e. Ethypharm customers for omeprazole in process of re-contracting with Lab. Belmac.
- f. Simvastatin approved earlier than expected – launched 17 Jan 2002, first to market! We will be manufacturing for approximately eight other companies also.
- g. Budget for 2002 in established products is for \$32 mil (approx 35% growth).
- h. Turned down opportunity to manufacture for Novartis – margins too low.
- i. Key personnel/staff changes:
  - Jose Maria (finance) retiring; Ester will replace
  - Fernando Bereunger retiring; new MD hired
  - Clemente Gonzales retiring; new MD hired
- j. Teva has committed to accelerate 15 new registrations through either Spain National Submission or the Mutual Recognition procedure. Teva is exploring acquisition of Bayvit

CONFIDENTIAL



B597

(No. 2 Generic in Spain). If this occurs, then the products would be transferred to Lab. Belmac/Davur.

k. Generic Drug Submissions for Yr 2002

**Laboratorios Belmac - YR 2002 Planned Generic Drug Submissions**

- |                                  |                              |
|----------------------------------|------------------------------|
| (3) *Omeprazole (Prilosec®)      | (2) Carbidopa-Levodopa       |
| (2) Bisoprolol 5 & 10mg          | (3) Pergolide (Permax®)      |
| (2) Doxazosine                   | (5) Lisinopril (Prinivil®)   |
| (1) Zolpiden (Ambien®)           | (3) Pravastatin (Pravachol®) |
| (2) Amox/Clavulanic (Augmentin®) | (4) Mirtazapine (Remeron®)   |
| (3) Amox/Clavulanic suspension   | (5) Fluconazole (Diflucan®)  |
| (1) Ibuprofen 100mg suspension   | (1) Famotidine (Pepcid®)     |
| (3) *Paracetamol sachets         | (2) Amoxicillin sachets      |
| (3) *Paracetamol tablets         | (3) Acetylcysteine           |
| (1) Paroxetine (Paxil®)          | (1) Naltrexone (ReVia®)      |
| (1) Amoxicillin suspension       |                              |

(#) = dosage levels      \* = BNT Patents

**2. Product Development**

a. Onychomycosis (Nail Lacquer) – The fingernail/toenail lacquer trials at the University of Alabama-Birmingham have continued to show excellent results. Trials (fingernail) will complete in March. Toenail Studies are trending even better than the Fingernail Studies. The PCT (Patent Cooperation Treaty) patent was filed worldwide and published in August 2001. Subsequent individual country filings are pending.

b. Intranasal Insulin –

- 1) Have source of insulin supply from Diosynth (Akzo-Nobel, Netherlands); insulin supply agreement signed.
- 2) Insulin cGMP manufacturing has been accomplished by BioConcepts Labs in Derry, NH.
- 3) Initial Proof of Principal trial in normal volunteers to be conducted in January (initiated on 18 Jan) in collaboration with the University of New Hampshire and a contract clinic.
- 4) Follow-on Phase I/II trials at the Diabetes and Glandular Disease Clinic, San Antonio, TX (PI - Sherwyn Schwartz) anticipated along with collaboration with GSK or another large company.

c. Testosterone for men – Phase III testosterone in men completed by Auxilium A2. The NDA was submitted 31 December. Working closely with Auxilium A2 on terms of disclosure and timing of press release for results and filing of NDA.

CONFIDENTIAL

B598

d. Androstanolone (DHT) and Oxycodone – Signed letter of intent with Auxilium A2. Funding provided from Auxilium for formulation development. Currently, Auxilium A2 is evaluating DHT formulations that we delivered to them. Oxycodone is on hold for the time being and may be substituted with another pain management agent.

e. Dartmouth – Testosterone gel trial in women with Fibromyalgia / Chronic Fatigue Syndrome commenced in December at the Dartmouth-Hitchcock Medical Center in Hanover, NH. Initial results with the first group of patients are promising. The trial will be continuing January - April with additional patients. An update on analysis of data for the first group is expected later this month from Dartmouth.

f. University of New Hampshire (UNH) Studies – Three studies/grants from the New Hampshire Industrial Research Committee in collaboration with UNH are in process. The third grant was approved this past summer. Studies include:

- 1) Formulation studies for nail lacquer, intranasal insulin spray
- 2) Hormone gels and intranasal spray testing in animals
- 3) Topical and intranasal study of the growth hormone (GnRH) for fertility applications

g. Paracetamol – Results of clinical study comparing paracetamol (1g sachet, two 500 mg tablets swallowed, and two 500 mg tablets dissolved) against reference drugs, Panadol® (GSK) and Tylenol® (McNeil), were completed in the third quarter last year. Results showed that Paracetamol outperformed both reference drugs by achieving maximum blood concentration in approximately one half the time of the reference drugs. Results announced in an October 2001 press release.

h. Simvastatin – Completed bioavailability studies of Simvastatin (Merck's Zocor®) – Bioequivalent and launched.

### 3. Licensing Activities

a. Pfizer – Following the successful Pfizer evaluation of our formulations (blind products) over the past 8 months, Pfizer signed a Research Collaboration Agreement with Bentley in December. The press release was issued on December 3rd. A joint working team has been formed, and Pfizer has agreed to fund \$310K for initial formulation development and in vitro testing (\$250K already received). Products include two veterinary products (Doramectin and Selamectin), and three unknown human products (one sexual health, and two anti-virals). Formulation development is in progress with in-vitro testing (human skin, Franz cell) planned for mid-February at DermTech.

#### b. Novartis –

- 1) Negotiations/agreements are in process for nail lacquer collaboration. Material Transfer Agreement and terms of agreement in process. Plan entails a multi-site Phase III trial for lacquers (with CPE-215) for potential actives: Terbinafine, Clotrimazole, Naftifine. Novartis wants to proceed with OTC as well as Rx. Visit to Basel, Switzerland to coordinate is scheduled for 5 February.

CONFIDENTIAL

- 2) Novartis also has continuing interest in a potential collaboration for paracetamol; discussion here is open and continuing.
- 3) Novartis asked to expand collaboration to include broad application of antifungals and other Rx products.

c. GlaxoSmithKline (GSK) –

- 1) Continuing interest in our intranasal insulin. GSK completed due diligence on us in July. After internal review by various groups/committees, GSK holding further progress until completion of our proof of principal insulin trial, which commences 18 January in North Hampton, NH.
- 2) GSK also interested in collaboration for transdermal formulation development.

d. Pharmacia – They have strong interest in our nail lacquer. Pharmacia conducted due diligence at Bentley in October. Notified us of intent to negotiate OTC license Jan/Feb. Negotiations/discussion of collaboration continuing.

e. Cambrex – Desire percentage interest in Bentley and establishment of JV Company to explore various product development in U.S. as well as generic filings in U.S. Exploratory discussions are underway.

f. Bristol Myers Squibb (BMS) – Continuing interest in intranasal insulin and other proprietary peptides. Meeting held 17 January.

g. Current licensing activity for paracetamol:

- Herron
- Sanofi
- Reckitt-Benckiser
- Perrigo
- Banner
- Chattem
- Angelini
- Bristol Myers Squibb
- Pharmacia
- Helm

h. Other Potential Drug Delivery, or other Company Collaborations are underway with:

- |                 |                      |
|-----------------|----------------------|
| • SkyePharma    | • Angelini           |
| • Perrigo       | • Schering AG/Berlex |
| • DUSA          | • Ardent Pharma      |
| • Lavipharm     | • DermTech           |
| • Chattem       | • Bio-Concepts Labs  |
| • Banner Pharma | • Labs Argenol       |
| • Helm          | • Medipointe         |
| • Bayvit/TEVA   | • Cephalon           |
| • Bayer         |                      |

CONFIDENTIAL



## Bentley Pharmaceuticals Project Status Report – January 29, 2002

PROJECT AND STATES	ACTION
<p>1. Pfizer</p> <ul style="list-style-type: none"> <li>Need to send new tox. studies as available from Auxilium. Bob Stote check status.</li> <li>Formulation work pending: 2 veterinary (Doramectin/Selamectin), 1 human/sexual health, and 2 antivirals. Formulations sent this week to DermTech for Franz cell testing.</li> </ul> <p>Note: Basic Agreements pending/planned: 1) Research Collaboration Agreement; 2) License (or Platform) Agreement; and 3) Subscription (investment) Agreement.</p>	<p>Bob continue formulation devel.</p> <p>Paul send tox. studies to Pfizer as available</p>
<p>2. DermTech</p> <ul style="list-style-type: none"> <li>In vitro human skin Franz cell testing. Bob G. sent Pfizer formulations to them this week, plus first payment for work to commence.</li> </ul>	<p>Bob/Paul monitor progress</p>
<p>3. GlaxoSmithKline (GSK)</p> <ul style="list-style-type: none"> <li>GSK (North Carolina) - Insulin <ul style="list-style-type: none"> <li>Joel talked to Jim. Joel is lobbying on our behalf. Some concern on formulation stability issue. Need to show results with our insulin clinical study (UNH/CHE).</li> </ul> </li> <li>GSK (Ian Buxton) – Transdermal Formulation Development. Jim emailed and called re. CDA and MTA. Ian is out until 14 Jan and then will call Jim.</li> </ul>	<p>Jim keep in touch with Joel</p> <p>Jim talk to Ian</p>
<p>4. Insulin – Development Issues</p> <p>a) <u>Supply</u> – Insulin supply from Diosynth. All OK for now.</p> <p>b) <u>Clinical Trials</u> -</p> <ul style="list-style-type: none"> <li>Proof of Principle Trial (in normals) at UNH – CAARD (Mark Windt Lab) <ul style="list-style-type: none"> <li>Third person to start trial on Friday 1 Feb. Expect a flat response based on first two patient glucose responses. Will need to begin re-formulating work with Bio-Concept.</li> </ul> </li> <li>Schwartz Lab – for Type 1 and Type 2 Diabetics <ul style="list-style-type: none"> <li>Project on hold pending completion of trial at CHE.</li> </ul> </li> </ul> <p>d) <u>Regulatory</u></p> <ul style="list-style-type: none"> <li>IND will be submitted prior to follow-on Phase I/II with Schwartz Lab</li> </ul>	<p>Bob S. sync visits with patient schedule</p> <p>Bob S. keep in touch with Schwartz lab.</p>
<p>5. Bio-Concept Laboratories</p> <ul style="list-style-type: none"> <li><u>Insulin</u> – Bob G. to meet with Frank Smith, et al, later this week to outline plans for ceasing work on current formulation and beginning re-formulation effort.</li> <li><u>Ophthalmic research</u> – Jim/Bob G. met with Frank Smith on 21 Nov and discussed two topics: Ophthalmic research planned for SBIR submission April 1<sup>st</sup>. Acquisition potential under review. Need to follow-up on intent with ophthalmic plan.</li> </ul>	<p>Bob/Paul coordinate with Bio-Concepts</p> <p>Jim/Jordan determine plan for ophthalmic collaboration</p>
<p>6. Novartis</p> <ul style="list-style-type: none"> <li>Anti-fungal Nail Lacquer <ul style="list-style-type: none"> <li>Visit to Basel, Switzerland planned 4-5 Feb (Jim, Bob G. and Jordan)</li> <li>MTA in process, however, needs revision per Jordan (has two problems: it's a one way and needs to be a two way; and it reflects all IP belonging to Novartis). Jim/Jordan to resolve separately.</li> </ul> </li> <li>Insulin – Jim received call from Bill Mann expressing interest in insulin. Follow-up required.</li> </ul>	<p>Attend Basel meeting</p> <p>Jordan track MTA progress</p> <p>Jim follow-up with Bill Mann.</p>

**CONFIDENTIAL**

B601



## Bentley Pharmaceuticals Project Status Report – January 29, 2002

PROJECT AND STATUS	ACTION
<ul style="list-style-type: none"> <li>Paracetamol (acetaminophen) - Jim provided samples to Mark Schobel at 19 Nov meeting. Prefer different taste.</li> </ul>	Jim get more paracetamol for Schobel.
7. Spain Phase III Lacquer Trial <ul style="list-style-type: none"> <li>Continue planning for possible trial in Spain. (Clotrimazole, Ciclopirox, Terbinafine?) Plans for trial in Spain will depend on plans with Novartis.</li> </ul>	Contingent on Novartis plans
8. Haarmann & Reimer (H&R) – Supply of CPE-215 <ul style="list-style-type: none"> <li>Paul obtained RIFM reference (Fassett/Wilson, 1961) from H&amp;R and provided to Pfizer with letter explaining irrelevance of reference (from Bob G).</li> <li>Need to complete the CDA with them. Was this ever done?</li> </ul>	Jordan respond to H&R on CDA
9. Auxilium A <sup>2</sup> <ul style="list-style-type: none"> <li>Testosterone in Men – NDA submitted 31 Dec (<u>not for publication</u>). Meeting held 14 Jan. <b>Results of meeting?</b></li> <li>Stanolone (DHT) – After 30 day stability on 6 formulations sent to them, will go into Yucatan pigs (Jan/Feb), then select 2 formulations to go into man before making an acceptance decision.</li> <li>Oxycodone – Formulation not releasing CPE-215. Either re-formulate, or look at another potential opiate.</li> <li>Other: Bob S. reported that tox. study reports will not be provided until Royalty agreement is completed. (need tox. reports to send to Pfizer)</li> </ul>	Bob S. check on status of stanolone and completion of new tox. studies.  Bob S / Bob G monitor DHT progress
10. UAB Nail Lacquer Clinical Study <ul style="list-style-type: none"> <li>Anti-fungal nail lacquer – Phase I/II Trials on-going at UAB. Latest update received from Wendy: 1/02/02.</li> </ul>	Bob S. monitor progress
11. Dartmouth-Bentley NHIRC Grant – Testosterone in women with Fibromyalgia (FMS) <ul style="list-style-type: none"> <li>Four patients completed study on 10 Dec. Data looks good. Meeting set for 14 Feb to discuss further.</li> <li>Two more groups of 4 patients planned: Expect to start Group 2 by mid-Feb. Must have all groups done by mid April. Trial insurance only thru mid-May. Also, Lin Brown goes on sabbatical (again) 24 April – 30 May.</li> <li>Bob to talk to Hillary about urgency of completing trial. Contractual requirements of license discussed. Jim may call Ala Kahn to express concern about slow progress.</li> </ul>	Bob/Paul get update from Hillary  Jim call Ala Kahn as necessary
12. UNH Projects – Summary <ul style="list-style-type: none"> <li>Project 1- Yvon Durant: Intranasal delivery, membrane transport. Current project ends 30 May 2002. <u>Two year grant extension has been approved</u>. Paul to work with UNH on getting Cooperative Agreement completed.</li> <li>Project 2 – Roger Wells: Delivery studies (pigs: testo, DHT, GnRH). Project ends May 2002. Any subsequent work will be on individual contract basis as needed.</li> <li>Project 3 – Stacia Sower: Peptide delivery (GnRH transdermally and intranasally. (Note: Roger Wells working in conjunction with Stacia to conserve resources). Topical has greater potential than the intranasal at this point.</li> </ul>	Paul work with UNH to complete Coop. Agmt for Durant extension

**CONFIDENTIAL**





B602

**Bentley Pharmaceuticals**  
**Project Status Report – January 29, 2002**

PROJECT AND STATUS	ACTION
13. Reckitt-Benckiser – Paracetamol sachet <ul style="list-style-type: none"> <li>Paracetamol sachet was reformulated for taste. Upon their request, we provided quotes for specific territories. <u>Pending Aug 2002 regulatory approval (Mutual Recognition).</u></li> </ul>	Jim monitor
14. Sanofi Synthelabo - Paracetamol tablets <ul style="list-style-type: none"> <li>Reformulating again for faster dissolution. Jim will follow-up. <u>Pending Aug 2002 regulatory approval (Mutual Recognition).</u></li> </ul>	Jim monitor
15. Cambrex <ul style="list-style-type: none"> <li>Discussion/negotiation in progress. New proposal drafted. We are now treating Cambrex as we would another licensee.</li> </ul>	Jordan send new proposal draft to Cambrex today
16. Vaccines - RIT (GSK in Belgium). <ul style="list-style-type: none"> <li>Bob S. to contact Jim Wright (U.S. contact) after Novartis deal worked out.</li> </ul>	Bob Stote call U.S. contact.
17. Bristol Myers Squibb – <ul style="list-style-type: none"> <li>Review of lacquer coming up. CDA is pending.</li> <li>Jim and Bob met with BMS on 17 Jan. Also interested in insulin and other peptides. Need to check on CDA/MTA.</li> </ul>	Jordan track CDA and MTA
18. Chattem <ul style="list-style-type: none"> <li>Contacted us on 10 Jan. Scientific Review Committee reviewing/interested in all areas, except lacquer. Paracetamol is our priority with them.</li> </ul>	Wait for their response
19. Herron - Paracetamol <ul style="list-style-type: none"> <li>Wants to license paracetamol for Australia and Pacific Rim. Adolfo sent term sheet. <u>Pending completion of regulatory submission Aug 2002 (Mutual Recognition).</u></li> </ul>	Jim follow-up
20. DUSA Pharm. <ul style="list-style-type: none"> <li>Interested in photo-active compounds with CPE-215. Also expressed interest in merging with us (this is premature). Next meeting planned for 4 April.</li> <li>CDA has been completed.</li> </ul>	Prepare for 4 April meeting
21. Perrigo Pharm. <ul style="list-style-type: none"> <li>Jim sent info package. Interested in generics, topical diclofenac. Awaiting call back.</li> </ul>	Jim follow-up
22. Banner Pharm. (North Carolina) <ul style="list-style-type: none"> <li>Banner is a contract manufacturer. They have requested 100 g of paracetamol to conduct informal taste masking studies. Paul contacted David Chance and they want to know if we are interested in a "chewable" form of paracetamol. Paul to follow up with David Chance to discuss potential meeting/visit. Will need to complete a CDA.</li> </ul>	Paul follow up
23. Bayer AG <ul style="list-style-type: none"> <li>Interested in our nail lacquer. Meeting planned for 4 Feb in Germany. (Jim and Bob G.)</li> </ul>	Jim/Bob G. visit Bayer 4 Feb
24. Ardent Pharmaceuticals <ul style="list-style-type: none"> <li>Paul contacted Phil Wise of Ardent. They are interested in pain, depression, and intranasal delivery. CDA completed. Paul setting up visit to their site in Durham, NC. sometime during month of March.</li> </ul>	Paul set up meeting with Ardent

**CONFIDENTIAL**



## Bentley Pharmaceuticals Project Status Report – January 29, 2002

PROJECT AND STATUS	ACTION
<p>25. Lavipharm Corporation – Potential acquisition of Lavipharm Corp. (U.S. arm of Lavipharm S.A. in Greece)</p> <ul style="list-style-type: none"> <li>▪ Paul/Jim to follow up with Jason Cale (London banking rep. handling auction for acquisition of Lavipharm Corp.). Need to obtain confidential company data on Financial terms, Product (licenses, patents), Facilities, Personnel.</li> <li>▪ CDA has been signed.</li> </ul>	<p>Paul/Jim obtain Lavipharm company data</p>
<p>26. Raymond James Stock Offering / Private Placement</p> <ul style="list-style-type: none"> <li>▪ Due diligence is underway. Currently in drafting stages for new stock offering/placement.</li> <li>▪ Continuing action per detailed event schedule.</li> </ul>	<p>Complete actions per event schedule</p>
<p>27. Insurance Issues</p> <ul style="list-style-type: none"> <li>▪ Tom Wilde passed issue on coverages in Europe to an international rep within Gallagher. He will be getting back to Mike.</li> <li>▪ Insulin trial insurance – Insurance for insulin trial completed. Cost is roughly \$6,400 due to total policy upgrade to \$2M- 5M through Essex Insurance. Tom Wilde to visit us on Friday 1 Feb.</li> </ul>	<p>Mike discuss international coverage issues</p> <p>Paul discuss clinical trial insurance</p>
<p>28. Tax Planning</p> <ul style="list-style-type: none"> <li>▪ Jordan/Mike completed document that addresses all issues and plan of action to minimize tax consequences with revenue in U.S. and transfer of IP between Bentley and subsidiaries. Follow-up at February BOD Meeting.</li> </ul>	<p>On hold until end of February</p>
<p>29. New Patents</p> <ul style="list-style-type: none"> <li>▪ <u>Patents – Spain</u> <ol style="list-style-type: none"> <li>a) 1<sup>st</sup> Patent – Submitted P-200002685 (General procedure – Vacuum and Granulation for other products.</li> <li>b) 2<sup>nd</sup> Patent – Submitted P-200002797 (Tablet formulation for Omeprazole and other gastric sensitive drugs – Direct compression.</li> <li>c) 3<sup>rd</sup> Patent – Organic formulation process for Omeprazole. Patent P-200100825. (also protection from Ethypharm).</li> <li>d) 4<sup>th</sup> Patent – Aqueous Process - a patent extension of the tablet formulation patent from last year (P-200002797). To be submitted early November 2001.</li> <li>e) 5<sup>th</sup> Patent – New procedure for tablets – direct compression. Plan to submit in December 2001.</li> <li>f) PCT for Paracetamol filed (Spanish Patent: P200002653)</li> </ol> </li> <li>▪ <u>Patents – Bentley</u> <ol style="list-style-type: none"> <li>a) Intranasal Insulin Patent – Bob G. filed the provisional in U.S. in June '01.</li> <li>b) Lacquer PCT published 23 Aug (PCT/US01/05302)</li> </ol> </li> </ul>	<p>Jordan and Bob G. to review patent issues. Jordan to have more oversight on patents</p>
<p>30. Labs Argenol – Potential Acquisition</p> <ul style="list-style-type: none"> <li>▪ Due diligence begins next week. Have only four products, but expect impressive sales growth next year. (Simvastatin is one of the products).</li> </ul>	<p>Jim monitor</p>

**CONFIDENTIAL**

B604



## Bentley Pharmaceuticals Project Status Report – January 29, 2002

PROJECT AND STATUS	ACTION
31. Bayvit – Acquisition <ul style="list-style-type: none"> <li>Bayvit acquisition is underway with TEVA with ultimate transfer to us.</li> </ul>	Jim monitor
32. BOD Meeting Schedule <ul style="list-style-type: none"> <li>Jan meeting postponed to 26-27 Feb in North Hampton.</li> </ul> <p><u>Other meetings:</u> The spring shareholder meeting is tentatively scheduled for May 22<sup>nd</sup>, don't want AMEX Board Rm, possibly the Penn Club. Jordan check with Miguel.</p>	Plan for Feb BOD meeting  Jordan follow up with Miguel on Penn Club
END LIST- OTHER POTENTIALS	
<ul style="list-style-type: none"> <li>PLR – Potential switch to other firm. Mike to ask Raymond James for recommendations.</li> <li>Helm – paracetamol</li> <li>SkyePharma – Spain, JV</li> <li>Stowic (client is Daiichi)- Paul attempting direct contact with Daiichi</li> <li>Medpointe</li> <li>Cephalon</li> <li>ICN</li> </ul> <p><u>Other Acquisition Potentials</u> - Dermtech, BioConcept Labs</p>	

**CONFIDENTIAL**



B605

Spain conf. CAM

1-30-01

(4)

Merck

10 yr rule - MON

Merck - Process Patent

Teva/BioGen - raw material

↳ Patent Different

CHIMOS - using also and licensed  
to others. Court  
deniedEthylpharmCANCELLED Agmt  
Equipment in FactoryUngrin

PATENTS + TRADEMARKS

Know-How

Challenge

3 SPAIN (2 over 1 yr)

2 PCT

1 Omeprazole Tablets (preparing)

10 Apr 2001

HIGHLY CONFIDENTIAL

BENTL000918

TO: DO UPON RETURN

Sales 372 W  
165 / 69000  
555  
1350  
1295  
155

1. Bayer - Email Dr.  
Propose Schedule

2. Jordan

Redacted

3. B. Satic

a. Memo

b. Terbinafine Plot

c. Clotrimazole, PH III

d. FDA Pre PH III meeting

e. Penlac? Fingernail

f. UAB - Fingernail when

4. ADOLFO

A. Protocol for PH III Clotrimazole

B. Protocol for PH I/II Terbinafine. oral, topical, clon

C. Ethypharm

D. MERCK

E. #Registries in Process - TEVA (15)

F. Novartis Proposal

G. PDR - Lacqum Oral

5. PREPARE FOR CONF. CALL

1. A 2002 % growth top line

2. Clinical - Auxilium - ?

DARTMOUTH

UAB - Fingernail

Insulin

UAB - TOENAIL

3. Licensing  
Lacqum  
Page 60  
Overview

B607

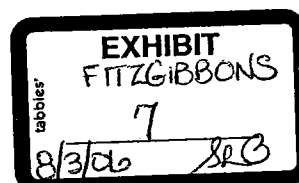
**From:** Paul Fitzgibbons  
**Sent:** Thu, 28 Feb 2002 18:14:02 GMT  
**To:** Jim Murphy; Bob Gyurik; 'Stote Bob (E-mail)'; Mike Price; Jordan Horvath  
**CC:**  
**BCC:**  
**Subject:** Management Meeting

---

Our next management meeting will occur on Friday, Mar 8th at 8:30. The attached project status report will be used for the meeting.

Paul Fitzgibbons  
Bentley Pharmaceuticals, Inc.  
603-964-8006 (office) 603-964-6889 (fax)  
pfitzgibbons@bentleypharm.com

---



BENTL023091  
HIGHLY CONFIDENTIAL



## Bentley Pharmaceuticals Project Status Report – January 29, 2002

PROJECT AND STATUS	ACTION
<p>1. Pfizer</p> <ul style="list-style-type: none"> <li>Need to send new tox. studies as available from Auxilium. Bob Stote check status.</li> <li>Formulation work pending: 2 veterinary (Doramectin/Selamectin), 1 human/sexual health, and 2 antivirals. Formulations sent this week to DermTech for Franz cell testing.</li> </ul> <p><u>Note:</u> Basic Agreements pending/planned: 1) Research Collaboration Agreement; 2) License (or Platform) Agreement; and 3) Subscription (investment) Agreement.</p>	<p>Bob continue formulation devel.</p> <p>Paul send tox. studies to Pfizer as available</p>
<p>2. DermTech</p> <ul style="list-style-type: none"> <li>In vitro human skin Franz cell testing. Bob G. sent Pfizer formulations to them this week, plus first payment for work to commence.</li> </ul>	<p>Bob/Paul monitor progress</p>
<p>3. GlaxoSmithKline (GSK)</p> <ul style="list-style-type: none"> <li>GSK (North Carolina) - Insulin <ul style="list-style-type: none"> <li>Joel talked to Jim. Joel is lobbying on our behalf. Some concern on formulation stability issue. Need to show results with our insulin clinical study (UNH/CHE).</li> </ul> </li> <li>GSK (Ian Buxton) – Transdermal Formulation Development. Jim emailed and called re. CDA and MTA. Ian is out until 14 Jan and then will call Jim.</li> </ul>	<p>Jim keep in touch with Joel</p> <p>Jim talk to Ian</p>
<p>4. Insulin – Development Issues</p> <p>a) <u>Supply</u> – Insulin supply from Diosynth. All OK for now.</p> <p>b) <u>Clinical Trials</u> -</p> <ul style="list-style-type: none"> <li>Proof of Principle Trial (in normals) at UNH – CAARD (Mark Windt Lab) <ul style="list-style-type: none"> <li>Third person to start trial on Friday 1 Feb. Expect a flat response based on first two patient glucose responses. Will need to begin re-formulating work with Bio-Concept.</li> </ul> </li> <li>Schwartz Lab – for Type 1 and Type 2 Diabetics <ul style="list-style-type: none"> <li>Project on hold pending completion of trial at CHE.</li> </ul> </li> </ul> <p>d) <u>Regulatory</u></p> <ul style="list-style-type: none"> <li>IND will be submitted prior to follow-on Phase I/II with Schwartz Lab</li> </ul>	<p>Bob S. sync visits with patient schedule</p> <p>Bob S. keep in touch with Schwartz lab.</p>
<p>5. Bio-Concept Laboratories</p> <ul style="list-style-type: none"> <li><u>Insulin</u> – Bob G. to meet with Frank Smith, et al, later this week to outline plans for ceasing work on current formulation and beginning re-formulation effort.</li> <li><u>Ophthalmic research</u> – Jim/Bob G. met with Frank Smith on 21 Nov and discussed two topics: Ophthalmic research planned for SBIR submission April 1<sup>st</sup>. Acquisition potential under review. Need to follow-up on intent with ophthalmic plan.</li> </ul>	<p>Bob/Paul coordinate with Bio-Concepts</p> <p>Jim/Jordan determine plan for ophthalmic collaboration</p>
<p>6. Novartis</p> <ul style="list-style-type: none"> <li>Anti-fungal Nail Lacquer <ul style="list-style-type: none"> <li>Visit to Basel, Switzerland planned 4-5 Feb (Jim, Bob G. and Jordan)</li> <li>MTA in process, however, needs revision per Jordan (has two problems: it's a one way and needs to be a two way; and it reflects all IP belonging to Novartis). Jim/Jordan to resolve separately.</li> </ul> </li> <li>Insulin – Jim received call from Bill Mann expressing interest in insulin. Follow-up required.</li> </ul>	<p>Attend Basel meeting</p> <p>Jordan track MTA progress</p> <p>Jim follow-up with Bill Mann.</p>

**CONFIDENTIAL**

1

BENTL023092  
HIGHLY CONFIDENTIAL

B609



## Bentley Pharmaceuticals Project Status Report – January 29, 2002

PROJECT AND STATUS	ACTION
<ul style="list-style-type: none"> <li>Paracetamol (acetaminophen) - Jim provided samples to Mark Schobel at 19 Nov meeting. Prefer different taste.</li> </ul>	Jim get more paracetamol for Schobel.
7. Spain Phase III Lacquer Trial <ul style="list-style-type: none"> <li>Continue planning for possible trial in Spain. (Clotrimazole, Ciclopirox, Terbinafine?) Plans for trial in Spain will depend on plans with Novartis.</li> </ul>	Contingent on Novartis plans
8. Haarmann & Reimer (H&R) – Supply of CPE-215 <ul style="list-style-type: none"> <li>Paul obtained RIFM reference (Fassett/Wilson, 1961) from H&amp;R and provided to Pfizer with letter explaining irrelevance of reference (from Bob G).</li> <li>Need to complete the CDA with them. Was this ever done?</li> </ul>	Jordan respond to H&R on CDA
9. Auxilium A <sup>2</sup> <ul style="list-style-type: none"> <li>Testosterone in Men – NDA submitted 31 Dec (<b>not for publication</b>). Meeting held 14 Jan. Results of meeting?</li> <li>Stanolone (DHT) – After 30 day stability on 6 formulations sent to them, will go into Yucatan pigs (Jan/Feb), then select 2 formulations to go into man before making an acceptance decision.</li> <li>Oxycodone – Formulation not releasing CPE-215. Either re-formulate, or look at another potential opiate.</li> <li>Other: Bob S. reported that tox. study reports will not be provided until Royalty agreement is completed. (need tox. reports to send to Pfizer)</li> </ul>	Bob S. check on status of stanolone and completion of new tox. studies.  Bob S / Bob G monitor DHT progress
10. UAB Nail Lacquer Clinical Study <ul style="list-style-type: none"> <li>Anti-fungal nail lacquer – Phase I/II Trials on-going at UAB. Latest update received from Wendy: 1/02/02.</li> </ul>	Bob S. monitor progress
11. Dartmouth-Bentley NHRC Grant – Testosterone in women with Fibromyalgia (FMS) <ul style="list-style-type: none"> <li>Four patients completed study on 10 Dec. Data looks good. Meeting set for 14 Feb to discuss further.</li> <li>Two more groups of 4 patients planned: Expect to start Group 2 by mid-Feb. Must have all groups done by mid April. Trial insurance only thru mid-May. Also, Lin Brown goes on sabbatical (again) 24 April – 30 May.</li> <li>Bob to talk to Hillary about urgency of completing trial. Contractual requirements of license discussed. Jim may call Ala Kahn to express concern about slow progress.</li> </ul>	Bob/Paul get update from Hillary  Jim call Ala Kahn as necessary
12. UNH Projects – Summary <ul style="list-style-type: none"> <li>Project 1- Yvon Durant: Intranasal delivery, membrane transport. Current project ends 30 May 2002. <u>Two year grant extension has been approved.</u> Paul to work with UNH on getting Cooperative Agreement completed.</li> <li>Project 2 – Roger Wells: Delivery studies (pigs: testo, DHT, GnRH). Project ends May 2002. Any subsequent work will be on individual contract basis as needed.</li> <li>Project 3 – Stacia Sower: Peptide delivery (GnRH transdermally and intranasally. (Note: Roger Wells working in conjunction with Stacia to conserve resources). Topical has greater potential than the intranasal at this point.</li> </ul>	Paul work with UNH to complete Coop. Agmt for Durant extension

**CONFIDENTIAL**

BENTL023093  
HIGHLY CONFIDENTIAL



**Bentley Pharmaceuticals**  
**Project Status Report – January 29, 2002**

PROJECT AND STATUS	ACTION
13. Reckitt-Benckiser – Paracetamol sachet <ul style="list-style-type: none"> <li>Paracetamol sachet was reformulated for taste. Upon their request, we provided quotes for specific territories. <u>Pending Aug 2002 regulatory approval (Mutual Recognition).</u></li> </ul>	Jim monitor
14. Sanofi Synthelabo - Paracetamol tablets <ul style="list-style-type: none"> <li>Reformulating again for faster dissolution. Jim will follow-up. <u>Pending Aug 2002 regulatory approval (Mutual Recognition).</u></li> </ul>	Jim monitor
15. Cambrex <ul style="list-style-type: none"> <li>Discussion/negotiation in progress. New proposal drafted. We are now treating Cambrex as we would another licensee.</li> </ul>	Jordan send new proposal draft to Cambrex today
16. Vaccines - RIT (GSK in Belgium). <ul style="list-style-type: none"> <li>Bob S. to contact Jim Wright (U.S. contact) after Novartis deal worked out.</li> </ul>	Bob Stote call U.S. contact.
17. Bristol Myers Squibb – <ul style="list-style-type: none"> <li>Review of lacquer coming up. CDA is pending.</li> <li>Jim and Bob met with BMS on 17 Jan. Also interested in insulin and other peptides. Need to check on CDA/MTA.</li> </ul>	Jordan track CDA and MTA
18. Chatterm <ul style="list-style-type: none"> <li>Contacted us on 10 Jan. Scientific Review Committee reviewing/interested in all areas, except lacquer. Paracetamol is our priority with them.</li> </ul>	Wait for their response
19. Herron - Paracetamol <ul style="list-style-type: none"> <li>Wants to license paracetamol for Australia and Pacific Rim. Adolfo sent term sheet. <u>Pending completion of regulatory submission Aug 2002 (Mutual Recognition).</u></li> </ul>	Jim follow-up
20. DUSA Pharm. <ul style="list-style-type: none"> <li>Interested in photo-active compounds with CPE-215. Also expressed interest in merging with us (this is premature). Next meeting planned for 4 April.</li> <li>CDA has been completed.</li> </ul>	Prepare for 4 April meeting
21. Perrigo Pharm. <ul style="list-style-type: none"> <li>Jim sent info package. Interested in generics, topical diclofenac. Awaiting call back.</li> </ul>	Jim follow-up
22. Banner Pharm. (North Carolina) <ul style="list-style-type: none"> <li>Banner is a contract manufacturer. They have requested 100 g of paracetamol to conduct informal taste masking studies. Paul contacted David Chance and they want to know if we are interested in a "chewable" form of paracetamol. Paul to follow up with David Chance to discuss potential meeting/visit. Will need to complete a CDA.</li> </ul>	Paul follow up
23. Bayer AG <ul style="list-style-type: none"> <li>Interested in our nail lacquer. Meeting planned for 4 Feb in Germany. (Jim and Bob G.)</li> </ul>	Jim/Bob G. visit Bayer 4 Feb
24. Ardent Pharmaceuticals <ul style="list-style-type: none"> <li>Paul contacted Phil Wise of Ardent. They are interested in pain, depression, and intranasal delivery. CDA completed. Paul setting up visit to their site in Durham, NC. sometime during month of March.</li> </ul>	Paul set up meeting with Ardent

**CONFIDENTIAL**





## Bentley Pharmaceuticals Project Status Report – January 29, 2002

PROJECT AND STATUS	ACTION
<p>25. Lavipharm Corporation – Potential acquisition of Lavipharm Corp. (U.S. arm of Lavipharm S.A. in Greece)</p> <ul style="list-style-type: none"> <li>• Paul/Jim to follow up with Jason Cale (London banking rep. handling auction for acquisition of Lavipharm Corp.). Need to obtain confidential company data on Financial terms, Product (licenses, patents), Facilities, Personnel.</li> <li>• CDA has been signed.</li> </ul>	Paul/Jim obtain Lavipharm company data
<p>26. Raymond James Stock Offering / Private Placement</p> <ul style="list-style-type: none"> <li>• Due diligence is underway. Currently in drafting stages for new stock offering/placement.</li> <li>• Continuing action per detailed event schedule.</li> </ul>	Complete actions per event schedule
<p>27. Insurance Issues</p> <ul style="list-style-type: none"> <li>• Tom Wilde passed issue on coverages in Europe to an international rep within Gallagher. He will be getting back to Mike.</li> <li>• Insulin trial insurance – Insurance for insulin trial completed. Cost is roughly \$6,400 due to total policy upgrade to \$2M- 5M through Essex Insurance. Tom Wilde to visit us on Friday 1 Feb.</li> </ul>	<p>Mike discuss international coverage issues</p> <p>Paul discuss clinical trial insurance</p>
<p>28. Tax Planning</p> <ul style="list-style-type: none"> <li>• Jordan/Mike completed document that addresses all issues and plan of action to minimize tax consequences with revenue in U.S. and transfer of IP between Bentley and subsidiaries. Follow-up at February BOD Meeting.</li> </ul>	On hold until end of February
<p>29. New Patents</p> <ul style="list-style-type: none"> <li>• <u>Patents – Spain</u> <ol style="list-style-type: none"> <li>a) 1<sup>st</sup> Patent – Submitted P-200002685 (General procedure – Vacuum and Granulation for other products.</li> <li>b) 2<sup>nd</sup> Patent – Submitted P-200002797 (Tablet formulation for Omeprazole and other gastric sensitive drugs – Direct compression.</li> <li>c) 3<sup>rd</sup> Patent – Organic formulation process for Omeprazole. Patent P-200100825. (also protection from Ethypharm).</li> <li>d) 4<sup>th</sup> Patent – Aqueous Process - a patent extension of the tablet formulation patent from last year (P-200002797). To be submitted early November 2001.</li> <li>e) 5<sup>th</sup> Patent – New procedure for tablets – direct compression. Plan to submit in December 2001.</li> <li>f) PCT for Paracetamol filed (Spanish Patent: P200002653)</li> </ol> </li> <li>• <u>Patents – Bentley</u> <ol style="list-style-type: none"> <li>a) Intranasal Insulin Patent – Bob G. filed the provisional in U.S. in June '01.</li> <li>b) Lacquer PCT published 23 Aug (PCT/US01/05302)</li> </ol> </li> </ul>	Jordan and Bob G. to review patent issues. Jordan to have more oversight on patents
<p>30. Labs Argenol – Potential Acquisition</p> <ul style="list-style-type: none"> <li>• Due diligence begins next week. Have only four products, but expect impressive sales growth next year. (Simvastatin is one of the products).</li> </ul>	Jim monitor

**CONFIDENTIAL**



**Bentley Pharmaceuticals**  
**Project Status Report – January 29, 2002**

PROJECT AND STATUS	ACTION
<p>31. Bayvit – Acquisition</p> <ul style="list-style-type: none"> <li>▪ Bayvit acquisition is underway with TEVA with ultimate transfer to us.</li> </ul>	<p>Jim monitor</p>
<p>32. BOD Meeting Schedule</p> <ul style="list-style-type: none"> <li>▪ Jan meeting postponed to 26-27 Feb in North Hampton.</li> </ul> <p><u>Other meetings:</u> The spring shareholder meeting is tentatively scheduled for May 22<sup>nd</sup>, don't want AMEX Board Rm, possibly the Penn Club. Jordan check with Miguel.</p>	<p>Plan for Feb BOD meeting</p> <p>Jordan follow up with Miguel on Penn Club</p>
END LIST- OTHER POTENTIALS	
<ul style="list-style-type: none"> <li>• PLR – Potential switch to other firm. Mike to ask Raymond James for recommendations.</li> <li>• Helm – paracetamol</li> <li>• SkyePharma – Spain, JV</li> <li>• Stowic (client is Daiichi)- Paul attempting direct contact with Daiichi</li> <li>• Medpointe</li> <li>• Cephalon</li> <li>• ICN</li> </ul> <p><u>Other Acquisition Potentials</u> - Dermtech, BioConcept Labs</p>	

**CONFIDENTIAL**





<http://www.ethypharm.com>

• Tel +33 1 4112 1720  
• Fax +33 1 4112 1730  
• E Mail [contact@ethypharm.com](mailto:contact@ethypharm.com)  
• Visioconf +33 1 4112 0075

194, Bureaux de la Colline -  
92213 SAINT CLOUD CEDEX- FRANCE

To	Mr James MURPHY	From	Mr Gérard LEDUC
Cie	BENTLEY	Cc	
Cc		Fax	+ 33 1 4112 29 89
Fax	001603 964 6889	Tel	+ 33 1 4112 1731
Tel	001 603 964 8006	e-Mail	<a href="mailto:leduc.gérard@ethypharm.com">leduc.gérard@ethypharm.com</a>
Page(s)		Date	April 18, 2002

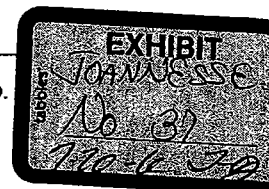
Dear Mr Murphy,

Please find attached for information purposes copy of the letter sent by our Spanish subsidiary, Ethypharm SA to your Spanish Subsidiary Belmac S.A..

Yours Sincerely,

Gérard LEDUC

IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, PLEASE NOTIFY US BY TELEPHONE AND  
CONSIDER THAT ANY DISSEMINATION, DISTRIBUTION OR COPY OF THIS FAX IS STRICTLY PROHIBITED.



EP 00247

B614

913199159



LABORATORIOS BELMAC S.A.  
C/Teide, 4  
Parque Empresarial "La Marina"  
28700 SAN SEBASTIAN DE LOS REYES (Madrid)

Madrid, 18 de abril de 2002

A/A D. Adolfo HERRERA – Director General

Apreciado Adolfo

He comentado nuestro caso con nuestros servicios jurídicos y me han confirmado lo que habíamos hablado por teléfono antes de tu viaje a los EEUU respecto a los pedidos y he aprovechado para pedirles su opinión respecto a los otros temas que han surgido en las conversaciones y correspondencia que venimos manteniendo entre nuestras compañías.

En lo que a los pedidos se refiere, es obvio que nuestros acuerdos quedaron sin efecto, por expiración del plazo pactado, el 23 de Marzo de 2002, pero esto no supone que las obligaciones contraídas por Belmac al respecto se hayan extinguido. Los pedidos formulados durante la permanencia en vigor de tales acuerdos subsisten después de su terminación. Como te expliqué vosotros aceptasteis esos pedidos y fijasteis incluso la fecha de entrega. No es necesaria por tanto negociación alguna sobre regímenes transitorios para dichos pedidos. Nuestra empresa se atiene al compromiso de entrega asumido expresamente en su día por Belmac. Ayer me ha llamado un cliente desesperado diciendo que tendrá ruptura de stock el próximo viernes 26, como sabes estos trabajan con el sistema "just in time". De cualquier forma no suministrar nos perjudica a todas las partes.

Referente a la utilización de la maquinaria me dicen que no podemos aceptar, como es natural, que la maquinaria propiedad de éthypharm en vuestra fábrica de Zaragoza, pueda ser utilizada para fines distintos de la mera fabricación de los pedidos pendientes de entrega. Dicha maquinaria no podrá ser utilizada, en consecuencia, en la fabricación del producto por parte de Belmac para su propio mercado y el de sus clientes como nos has expuesto en la última carta.

Por otro lado y además si quisierais continuar/persistir en el propósito de fabricar vuestro propio producto, debo recordaros que la patente española 9301319 propiedad de ethypharm confiere a nuestra empresa un derecho de exclusiva sobre la formulación de microgránulos de omeprazol y el procedimiento para su obtención. Te ruego por lo

Marqués de la Ensenada, 16 - Centro Colón 28004 Madrid (España)  
TEL : +34 913 085 581 - FAX +34 913 199 159  
Correo-e: ethypharm@ethypharm.es Pág Web: http://www.ethypharm.com

HEURE DE RÉCEPTION 18. AVR. 19:32

HEURE D'IMPRESSION 18. AVR. 19:33

EP 00247

Registre Mercantil de Madrid n.º 1, tomo 111, g.º 5, n.º 5, folio 132, M. 114511, I. 1, J. 1, A. 2811404

913199159



tanto que os abstengáis de cualquier acto de explotación que incida en el ámbito de nuestra patente.


Como fundamentación de lo anterior emitisteis un comunicado (Bentley) y según la información que me transmitiste habéis descubierto y protegido un sistema propio de fabricación del omeprazol. Entiendo que siendo así, con el fin de evitar cualquier conflicto en materia de patentes, te pido que nos facilitéis toda la información necesaria para que nuestros técnicos y asesores legales determinen hasta qué punto dicho procedimiento escapa del ámbito de la patente de invención 9301319. Al tratarlo con ellos me han explicado y me han hecho entender y tu comprenderás que no se trata sólo de una cortesía comercial obligada después de tantos años de relaciones entre nuestras compañías, sino de una exigencia legal.

Aprovecho para transmitirte otro tema delicado que ha llegado a nuestro conocimiento según el cual Belmac pudiera estar atendiendo / dirigiéndose a clientes de ethypharm, para ofrecerles su propio producto. En principio me extraña que esto sea así dadas las conversaciones y comentarios que me has hecho en el pasado. De todas formas comprenderás, que si esto fuese así, me vea obligado a llamar tu atención sobre el carácter desleal que una práctica de esta clase podría revestir y de las sanciones legales que se contemplan al efecto.

Confío en que las diferencias surgidas entre nuestras compañías puedan ser superadas teniendo presente la relación comercial tan dilatada en el tiempo que hemos mantenido y el soporte que ethypharm ha representado siempre para Belmac en tantos aspectos. Es nuestro deseo que podamos encontrar una solución ahora y para los temas que nos quedan por debatir en el futuro. Te ruego, en esta misma línea, una respuesta con la mayor brevedad, para que nuestra empresa pueda adoptar en su caso las medidas que estime más oportunas en defensa de sus derechos e intereses.

No quisiéramos tener que haceros responsables de los daños y perjuicios que supondría para ethypharm la inobservancia por Belmac de sus compromisos contractuales sobre los pedidos pendientes o de aquellos otros que se producirían de una violación de nuestros derechos de patente. Pero debéis ser conscientes de que nuestra empresa, junto a su mejor voluntad para resolver este asunto de un modo amistoso, tiene el propósito firme de no hacer dejación alguna de sus derechos.

En espera de tus noticias y quedando a tu disposición para cualquier aclaración que precises te saluda cordialmente.

  
Fdo.: ETHYPHARM, SA  
D. Adolfo de Basilio

HEURE DE RÉCEPTION 18. AVR. 19:32

HEURE D'IMPRESSION 18. AVR. 19:33

EP 00247

B616

P. 1

\* \* \* Rapport de TRANSMISSION ( 18. Avr. 2002 20:33 ) \* \* \*

T T I ETHYPHARM ST CLOUD 33 1 41121718

Fich	Mode	Option	Adresse (Groupe)	Résultat	Page
4177	TX_MEM		G3:00016039646889	OK	P. 3/3

Cause de l'erreur  
 1) Recroché ou erreur ligne 2) Occupé 3) Pas de réponse  
 4) Pas un télécopieur 5) Dépassement des 3 min.


<http://www.ethypharm.com>

• Tel	+33 1 4112 1720
• Fax	+33 1 4112 1730
• E Mail	contact@ethypharm.com
• Visioconf	+33 1 4112 0075

194, Bureaux de la Colline - 92213 SAINT CLOUD CEDEX- FRANCE
---

To	Mr James MURPHY	From	Mr Gérard LEDUC
Cie	BENTLEY	Cc	
Cc		Fax	+ 33 1 4112 29 89
Fax	001 603 964 6889	Tel	+ 33 1 4112 1731
Tel	001 603 964 8006	e-Mail	leduc.gérard@ethypharm.com
			April 18, 2002
Page(s)		Date	

Dear Mr Murphy,

Please find attached for information purposes copy of the letter sent by our Spanish subsidiary, Ethypharm SA to your Spanish Subsidiary Belmac S.A..

EP 00247

B617

913199159

[logo] **Ethypharm**  
Drug delivery solutions

LABORATORIES BELMAC S.A.  
C/ Teide, 4  
Parque Empresarial "La Marina"  
28700 SAN SEBASTIAN DE LOS REYES (Madrid)

Madrid, April 18, 2002

Mr. Adolfo HERRERA – Director General

Dear Adolfo

I have discussed our case with our legal services and they have confirmed to me what we spoke about by telephone before your trip to the USA concerning the orders, and I have taken the opportunity to ask them their opinion concerning the other matters that have arisen in the conversations and correspondence which we have been maintaining between our companies.

As far as the orders are concerned, it is obvious that our agreements were rendered without effect, due to expiry of the agreed period on March 23, 2002, but this does not mean that the obligations contracted by Belmac in this regard have extinguished. The orders formulated during the period those agreements were in force still remain after termination. As I explained to you, you accepted those orders and you even set the delivery date. Therefore, no negotiation at all is necessary concerning transition regimes for those orders. Our company abides by the delivery commitment expressly assumed at the time by Belmac. Yesterday I had a call from a desperate client who will have a stock outage next Friday the 26<sup>th</sup>, as you know these people work on the "just-in-time" system. At any rate not supplying is detrimental to all parties.

With respect to use of the machinery they tell me that, naturally, we cannot accept that machinery owned by Ethypharm in your factory in Saragossa can be used for purposes other than the simple manufacture of the orders awaiting delivery. Consequently, that machinery cannot be utilized in the manufacture of the product by Belmac for its own and its clients' market as you have put it to us in your last letter.

Furthermore and moreover, if you do wish to continue/persist in your intention to manufacture your own product, I must remind you that Spanish patent 9301319 owned by Ethypharm confers upon our company an exclusive right over the formulation of omeprazole microgranules and the procedure for obtaining them. I therefore respectfully request

Marques de la Ensenada, 16 - Centro Colon 28004 Madrid (Spain)  
TEL: +34 913 085 581 - FAX +34 913 100 159  
Email: ethypharm@ethypharm.es Webpage: <http://www.ethypharm.com>

TIME RECEIVED 18 APR. 19:32

TIME PRINTED 18 APR 19:33

Madrid commercial Registry No. 1 Volume 1001, gen 978, Sec 3, Page 312 H 72445-1 IF A 7818404

EP 002472

913199159

[logo]

**Ethypharm**  
Drug delivery solutions

that you refrain from any act of commercial use that infringes upon the area of our patent.

Based on the above arguments you issued a communication (Bentley), and according to the information you sent me you have discovered and protected your own system for manufacturing omeprazole. If this is the case then in my view, and with the purpose of avoiding any conflict regarding patents, I ask that you provide us with all the necessary information so that our technical personnel and legal advisers can determine to what point your procedure falls outside the scope of invention patent 9301319. When I discussed it with them they explained it to me and made me understand [sic], and you will appreciate that this is not just an obligatory commercial courtesy after so many years of relations between our companies, but rather a legal requirement.

I would also like mention to you another delicate matter which has come to our knowledge, namely the possibility Belmac might be attending/addressing itself to Ethypharm clients to offer them its own product. First and foremost I am surprised this should be so given our conversations and the comments you have made to me in the past. In any case you will understand, that if this were the case, I would be obliged to call your attention to the bad faith that this kind of practice could reveal, and the legal sanctions which apply in that regard.

I trust that the differences that have emerged between our companies can be overcome, considering the lengthy commercial relationship we have maintained over time and the support that Ethypharm has always represented for Belmac in so many aspects. It is our wish that we can find a solution now and also for the matters that remain for us to discuss in the future. Therefore in the same vein I respectfully seek a reply from you at your earliest convenience, so that our company can accordingly adopt whatever measures it deems most appropriate in defense of its rights and interests.

We would not wish to hold you liable for the damages and losses that would be entailed for Ethypharm if Belmac breaches its contractual commitments concerning pending orders or other orders which would be produced by violating our patent rights. But you must be aware that our company, together with its best will in resolving this matter in an amicable fashion, also holds firm in its intention not to abandon any of its rights.

I look forward to your reply, and will be pleased to supply you with any clarification you may require.  
Yours sincerely,

[signature]

Signed: ETHYPHARM, SA  
Adolfo de Basilio

TIME RECEIVED 18 APR 19:32

TIME PRINTED 18 APR 19:33

EP 002473

B619

[see source for English/ French]

EP 002474

B620

**From:** pharmalliance [pharmalliance@hotmail.com]  
**Sent:** 07/18/2002  
**To:** Ignacio Alvarez [I.A.G.P@terra.es]  
**Cc:**  
**Bcc:**  
**Subject:**

Dear Ignacio,

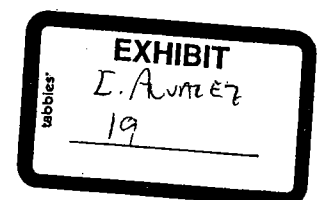
I received an e-mail message from JP Lacombe menacing Pharmalliance concerning the product Omeprazole. I defend myself because as you know I didn't sign any contract with Ethypharm concerning Omeprazole. He told me a lot of things and that they are in a justice procee with Belmac because they are using Ethypharm know how and Ethypharm machinery to manufacture omeprazole...

I denied that today Pharmalliance is buying its omeprazole from Belmac, and ask him to recheck his information sources.

Cordially,

Amal

CONFIDENTIAL



BEL003925



B621

# Presentation to Perrigo

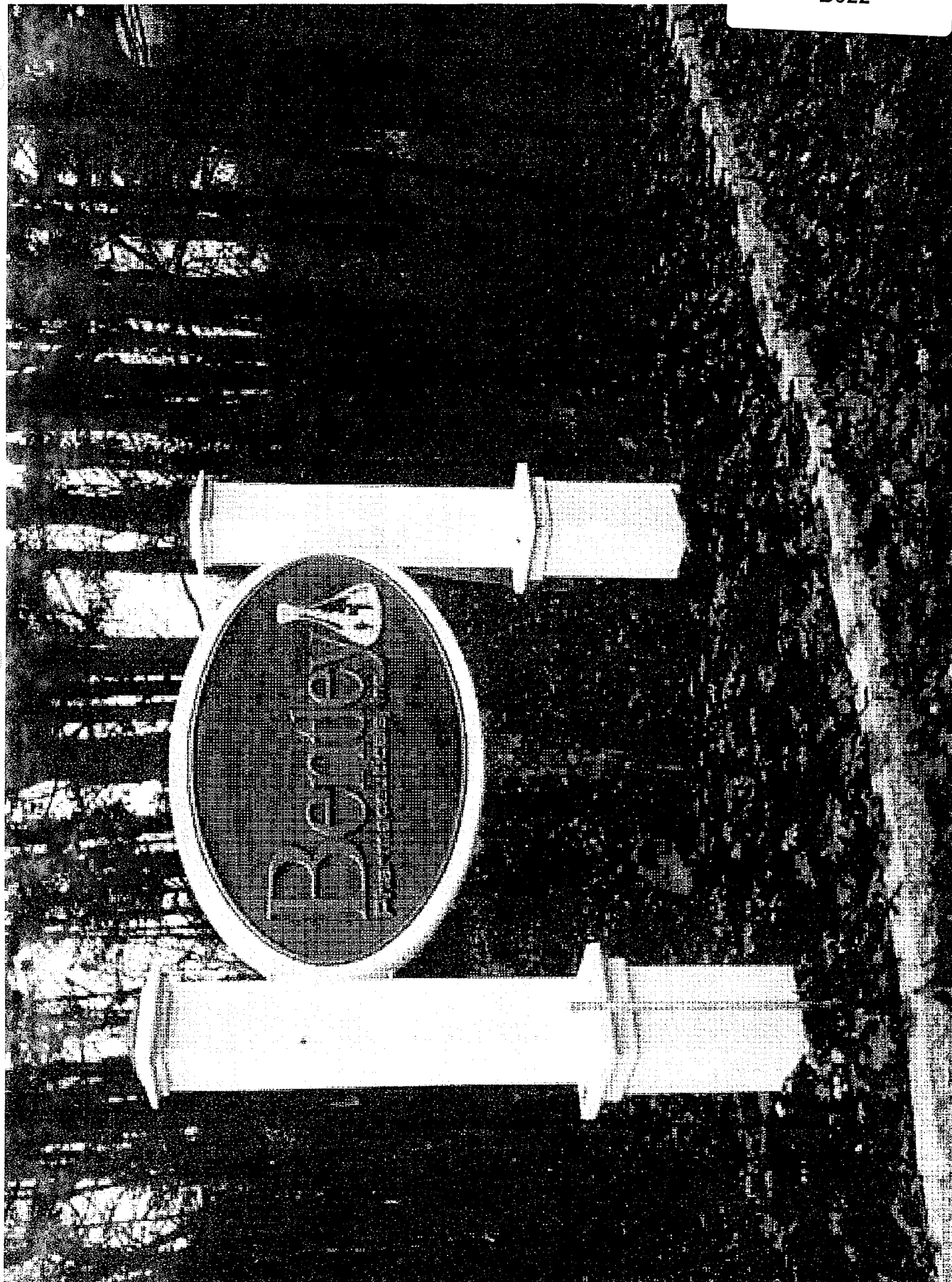
Bentley Pharmaceuticals

- Topical Drug Delivery
- Intranasal Drug Delivery



BENTL022782  
CONFIDENTIAL

B622



BENTL022783  
CONFIDENTIAL

B623

# Bentley operations

Bentley HQ – Exeter NH, USA

## Bentley Divisions

Belmac – Zaragoza & Madrid, Spain - Branded

Rimafar – Madrid, Spain - OTC's

Davur – Madrid, Spain - Generics

[www.bentleypharm.com](http://www.bentleypharm.com)



Confidential property of Bentley Pharmaceuticals 2003

BENTL022784  
CONFIDENTIAL



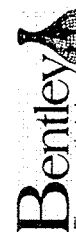
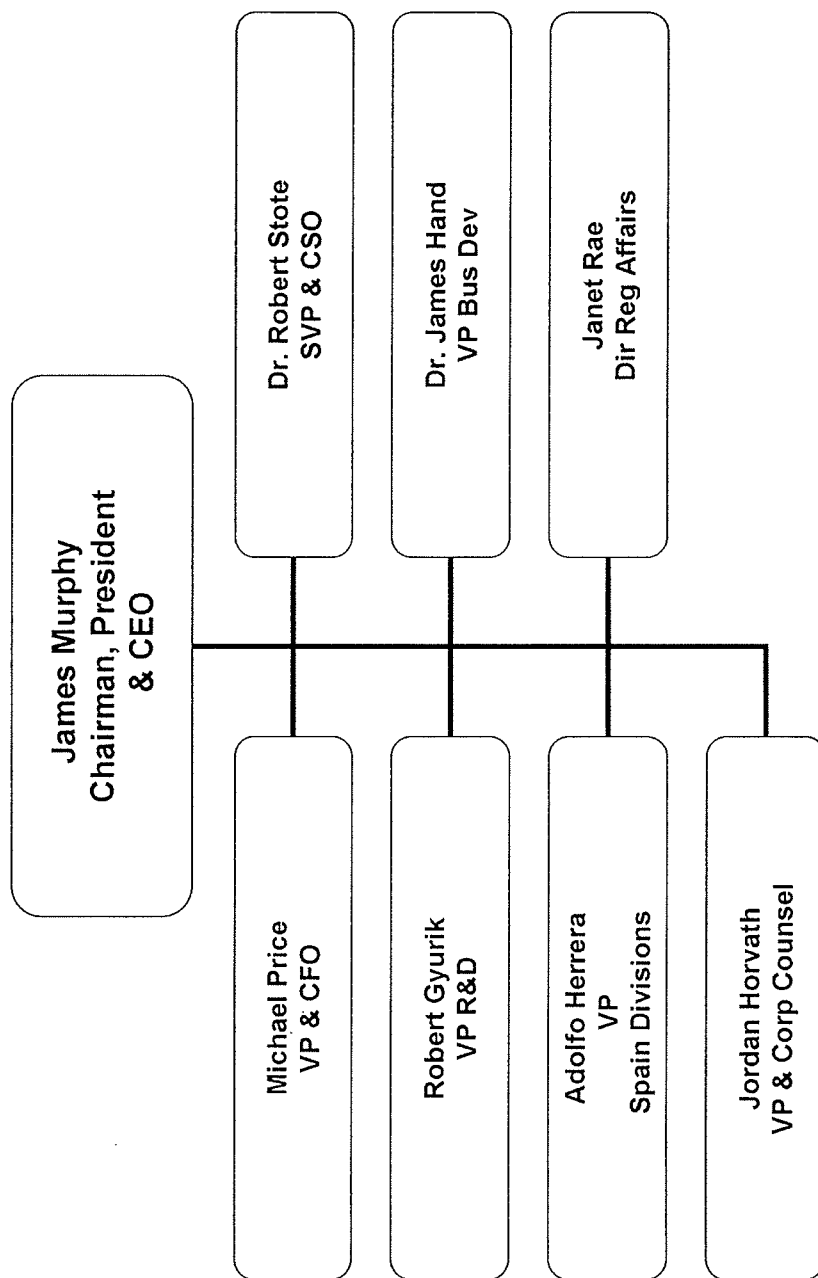
B624



BENTL022785  
CONFIDENTIAL

B625

# Bentley management



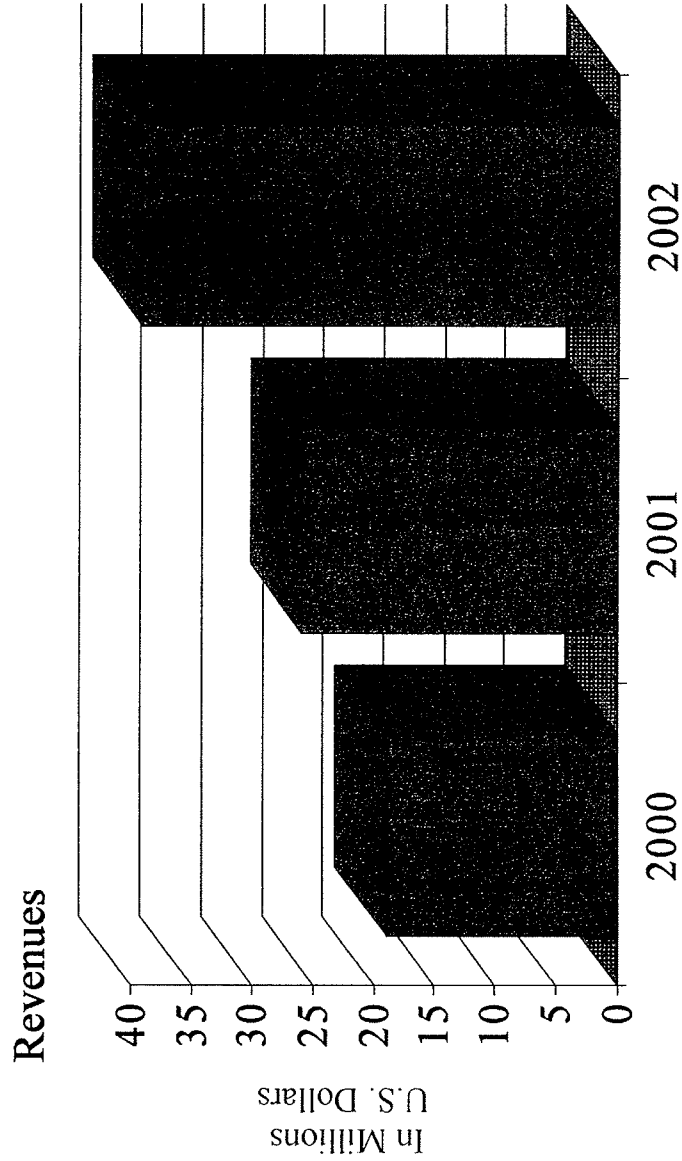
Confidential property of Bentley Pharmaceuticals 2003

BENTL022786  
CONFIDENTIAL

# Financial Highlights

## *Consistent Revenue Growth*

Historical Performance



Confidential property of Bentley Pharmaceuticals 2003

B626

BENTL022787  
CONFIDENTIAL

B627

# Financial Highlights

## *Strong Balance Sheet*

Selected Balance Sheet Data

	<u>December 31,</u>	
	<u>2002</u>	<u>2001</u>
Working capital	\$30,703	\$6,276
Non-current assets	20,720	16,280
Total assets	64,692	32,119
Non-current liabilities	2,672	2,132
Stockholder's equity	48,751	20,424
		17,816

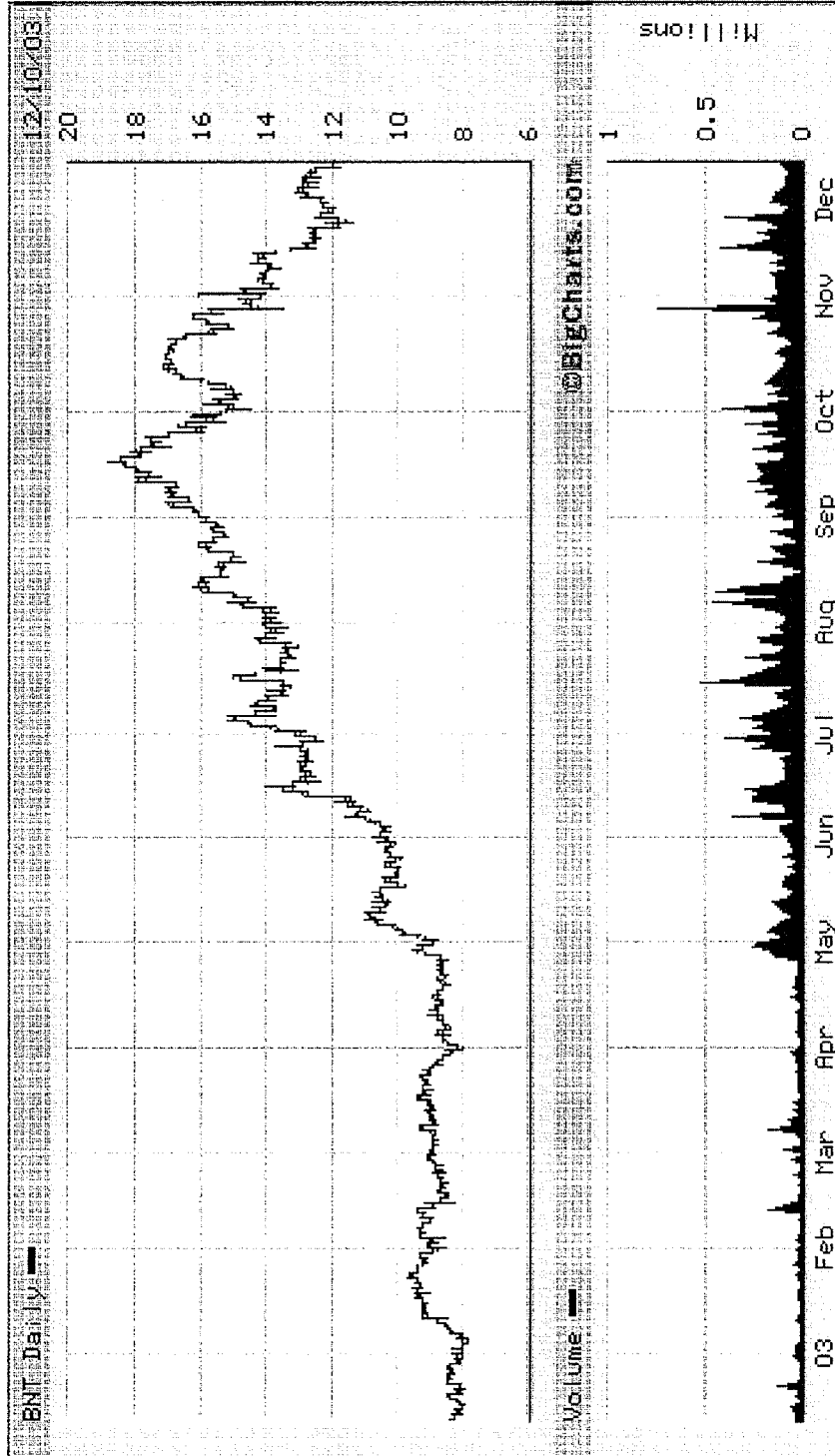


Confidential property of Bentley Pharmaceuticals 2003

BENTL022788  
CONFIDENTIAL

B628

# Stock performance



Confidential property of Bentley Pharmaceuticals 2003

BENTL022789  
CONFIDENTIAL